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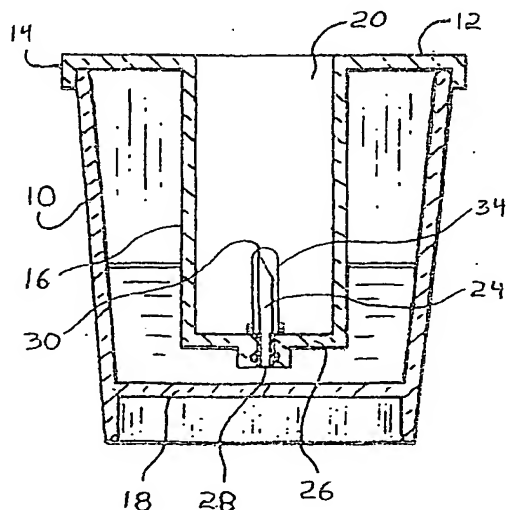
(30) Priority: **19.09.2001 US 323371**

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(54) **Liquid specimen collection container.**

(57) A container assembly provides for the collection, transporting, and dispensing of a fluid specimen. The container assembly includes a cup-shaped container having an open end for collecting the fluid specimen. A lid is attachable to the container to close the open end thereof. The lid includes a receptacle for providing communication with the collected fluid specimen through the cover and for permitting extraction of a sample there-

from. A self-sealing closure member is supported by the lid in the receptacle and seals the receptacle preventing fluid leakage. The extraction device may be used to extract a sample of the fluid specimen. The extraction device is insertable into the receptacle to permit such extraction. Upon removal of the extraction device, the self-sealing closure reseals the container and prevents fluid leakage into the receptacle.

FIG. 2

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to a cup container used for collecting urine or other biological liquid specimens. An air-evacuated container may be used to extract portions of the specimen from the sealed container without removing the lid. The transfer may be done without pouring or pipetting.

2. Description of Related Art

[0002] In order to conduct laboratory testing on biological fluid samples such as urine, it is necessary to provide a container for collecting urine specimens. These specimen collection containers typically include a cup-shaped container with a removable cover. Once the sample has been collected in the container, the cover is reapplied. The specimen collection container may then be transported to a laboratory or other testing facility where a sample of the collected specimen is extracted for test purposes.

[0003] In order to simplify the sample extraction process, the prior art has seen the use of covers which not only cover and seal the collection container, but also provide for the use of an extraction device which permits the extraction of a sample of the fluid specimen. Such covers may include a sample port which supports a tube extending from the sample port to the lower end of the cup-shaped container in fluid communication with the specimen contained therein. The tube may include at its upper end a needle which extends to a location at the level of or above the cover so that at an air-evacuated collection container, such as a specimen collection tube, may be attached thereto to draw a portion of the collected sample thereinto without removal of the cover and removed without spilling or contaminating the sample port area. Subsequent samples may be drawn from the specimen collection container by using plural collection tubes.

[0004] Many of the prior art devices support the needle in the cover at the upper end of the collection container. The needle is generally exposed and may result in an accidental needle stick. Some prior art devices include a cap to cover the sample port opening or the needle tip itself to fully seal the specimen container and to prevent injury from an accidental needle stick when handling the sealed container. However, the caps must be removed in order to draw a sample of the specimen and replaced afterwards, exposing the user to risk of a needle stick at those times. Further, the needle contained in the cover is a separate metallic insert which must be disposed of as a sharps device.

[0005] It is, therefore, desirable to provide an improved specimen collection container which safely col-

lects, transports and dispenses a fluid specimen and which can be easily and safely disposed of after use.

SUMMARY OF THE INVENTION

[0006] According to the present invention, a container assembly for safely collecting, transporting and dispensing a fluid specimen, which can be easily and safely disposed of, e.g. by incineration, is provided.

[0007] In one aspect, the invention relates to a container assembly which includes a cup-shaped container having sidewalls joining a bottom wall and an opposed open end to define a container interior for collecting a fluid specimen, a lid attachable to the container to close the open end thereof, a cannula and a self-sealing closure member.

[0008] The lid has a central portion, a peripheral margin, a sealing flange at the periphery of the peripheral margin and a continuous, elongated receptacle having an opening located within the central portion for insertable receipt of an evacuated tube having a cannula pierceable stopper. The peripheral flange extends from the peripheral margin towards the bottom wall of the container and sealingly engages the open end of the container when the lid is sealed on the container. The elongated receptacle includes a lower wall extending from the central portion of the lid into the container interior and towards the bottom wall of the container when the lid is placed on the container.

[0009] The cannula is supported by the lower wall of the receptacle and has a first needle end positioned within the receptacle at a depth into the opening substantially below the sealing flange, in a position to pierce the stopper of an evacuated tube when the tube is received with its pierceable stopper end first into the receptacle, and a second needle end positioned within the container interior, when the lid is placed on the container, so that communication between the container and the tube is established when the tube is inserted in the receptacle.

[0010] The self-sealing closure member prevents fluid communication between the container and the receptacle, allowing communication between the container and the tube when the tube is inserted in the receptacle and being self-sealing to prevent fluid communication between the container and the receptacle when the tube is retracted from the receptacle.

[0011] In one embodiment, the bottom wall of the container has an inner convex shaped surface and an outer concave shaped surface. Preferably, the container is transparent. The container can also have a fill level indicator which identifies the maximum fill level for collecting a fluid specimen. The fill level indicator is located so that the fluid specimen will not exceed the capacity of the container when the container is initially filled to the fill level indicator and then the lid is placed on the container.

[0012] Preferably, the elongated receptacle is gener-

ally cylindrical for accommodating an evacuated collection tube. In one embodiment, the opening of the elongated receptacle is offset from the center of the central portion of the lid, towards the peripheral margin of the lid, and the lower wall of the receptacle extends toward the bottom wall of the container at a location offset from the center of the bottom wall, towards the sidewalls, when the lid is placed on the container.

[0013] Preferably, the lower wall of the elongated receptacle extends to a distance of less than about 2 cm from the bottom wall of the container when the lid is placed on the container and, more preferably, less than about 1 cm from the bottom wall of the container when the lid is placed on the container.

[0014] The cannula is preferably formed of a polymeric resin. The cannula is also preferably molded in place on the lower wall of the elongated receptacle. More preferably, the cannula is continuous with and part of the molded surface of the lower wall of the receptacle. Preferably, the second needle end of said cannula is flush with the lower wall of the elongated receptacle. While a polymeric integrally molded cannula is preferred, the present invention also contemplates use of a stainless cannula which may be bonded in place.

[0015] In an embodiment where the container includes a fill level indicator, the first needle end of the cannula is positioned at a location within the receptacle at a depth from the opening substantially below the fill level indicator when the lid is placed on the container.

[0016] The first needle end is preferably positioned at a location within the receptacle such that the ratio of the distance between the opening of the receptacle and the first needle end to the distance between the lower wall of the receptacle and the first needle end is at least about 3:1 and, more preferably, at least about 4:1.

[0017] The first needle end is also preferably positioned at a location within the receptacle at a distance of less than about 2.0 cm from the lower wall of the receptacle and, more preferably, less than about 1.5 cm from the lower wall of the receptacle.

[0018] The self-sealing closure member is preferably a cannula pierceable self-sealing sleeve covering the first needle end of the cannula to prevent fluid communication between the container and the receptacle. The sleeve is pierceable to allow communication between the container and an evacuated tube when the tube is inserted in the receptacle and is self-sealing to prevent fluid communication between the container and the receptacle when the tube is retracted from the receptacle.

[0019] The sleeve is preferably a unitary device molded from a flexible, elastomeric material capable of re-sealing after being pierced by the cannula.

[0020] An advantage of the present invention is that it allows a patient and/or an operator to safely collect, transport and dispense a fluid biological specimen and otherwise safely handle the container assembly, without risk of an accidental needle stick.

[0021] Another advantage of the present invention is

that, once the lid is sealed on the container, the operator can transport and dispense a fluid specimen without risk of contaminating the fluid specimen or the dispensed fluid sample, or being contaminated by the biological specimen.

[0022] Yet another advantage, in the case of a polymeric molded cannula, is that the container assembly can be easily and safely disposed of after use, e.g., by incineration, without the need to separately dispose of biological sharps, e.g., a metal needle.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] FIG. 1 is an isometric view of the container and lid of an embodiment of the present invention;

[0024] FIG. 2 is a cross-sectional side elevation of the container and lid of FIG. 1;

[0025] FIG. 3 is a view similar to FIG. 2 with an air-evacuated tube inserted in the receptacle and forced over the needle point.

[0026] FIG. 4 is a side elevation of a preferred embodiment container of the invention with a cross-sectional view of one side showing the receptacle.

[0027] FIG. 5 is an isometric view of the lid component employed in the preferred embodiment container of FIG. 4.

[0028] FIG. 6 is a cross-sectional, side elevation of the lid component shown in FIG. 5.

[0029] FIG. 7 is a view similar to FIG. 6 with an air-evacuated tube inserted in the receptacle and forced over the needle point.

DETAILED DESCRIPTION OF THE INVENTION

[0030] The present invention provides a specimen collection assembly for safely collecting, transporting and dispensing a fluid specimen and allows for samples to be drawn from the specimen safely and without contamination of the specimen.

[0031] One embodiment of the invention provides a specimen collection container assembly that includes a cup for collecting liquid specimens and a lid having a receptacle and a cannula for use with an evacuated tube for withdrawing samples of the specimen. Referring to the drawings there is shown in FIGS. 1-3 a cup 10 in which urine or other biological liquid specimens may be collected after which the patient or supervising nurse places a lid 12 on the cup.

[0032] The lid 12 has a flange 14 around its outer rim of a size to provide a tight fit when the lid is placed over the cup 10. The lid has an elongated receptacle 16 extending into the container towards the bottom wall of the cup 18 for insertable receipt of an evacuated tube having a cannula pierceable stopper. The receptacle 16 has an opening 20 for insertable receipt of an evacuated tube 22 and a cannula 24 passing through its lower wall 26 with the lower end of the cannula 28 flush with the lower wall 26 of the receptacle or extending further to-

wards the bottom of the cup. The top end of the cannula projects through the lower wall of the receptacle so that its needle point 30 is adapted to pierce the stopper 32 of an air-evacuated tube 22 for withdrawing liquid from within the cup. The needle point of the cannula 30 is recessed within the receptacle 16 at a depth into the opening 20 sufficient to prevent injury to a patient or attendant when collecting a specimen, handling the container or withdrawing a sample of the specimen. The needle point of the cannula 30 is recessed within the receptacle at a depth from the opening 20 below the sealing flange 14. The receptacle also has a self-sealing closure member 34 positioned to prevent fluid communication between the container interior and the receptacle. The self-sealing closure member 34 is preferably cannula pierceable to allow communication between the container interior and the evacuated tube when the tube is inserted in the receptacle and is self-sealing to prevent fluid communication between the container interior and the receptacle when the tube is retracted from the receptacle.

[0033] When a sample of the specimen is to be removed from the cup it is only necessary to place the stopper end of the air-evacuated tube 22 into the receptacle so that the needle pierces the stopper 32 of the tube 22. Since it is not necessary to remove the lid 12 and the needle point remains isolated from the receptacle as a result of the self-sealing closure member, no outside contamination of the tube 22 occurs. Furthermore, following shaking or mixing of the specimen, liquid does not run down the outside of the cup as with most specimen cups requiring removal of the lid. If the air-evacuated tube 22 containing either a urine preservative or a sputum digestant is placed on the needle, there will be no contamination of the specimen container or tube 22 when it is sent to the laboratory. This method provides a means for reducing the possibility of contaminating the nurse and laboratory worker with infectious agents present in the specimen by eliminating the need for pouring or pipetting portions of the specimen to several containers for processing by various departments in the laboratory.

[0034] Those skilled in the art will appreciate that many variations of the above described embodiment of the invention may be made without departing from the spirit and the scope of the invention. For example, referring now to FIG. 4, there is seen a side elevation of a preferred embodiment collection container assembly 36 of the invention with a cross-sectional view of one side of the container assembly 36 which includes a receptacle for receiving an evacuated sample tube. The container assembly 36 comprises a cup 38 portion and a removable lid 40 portion. The cup 38 comprises a slightly tapering, tubular vessel having continuous, tapered sidewalls 42 separating an open end 44 and a closed end 46. The closed end 46 has a convex shaped inner surface 48 and a concave shaped outer surface 50 to assist in maximum sample collection of small vol-

ume fluids in the bottom of the cup 38. The lid 40 is removably attached on the open end 44 of cup 38. The cup 38 with lid 40 together define a collection chamber 52 which is suitable for holding biologically hazardous materials. The cup 38 and lid 40 may be fashioned from any conventional material such as, for example, a polymeric resin. Polymeric resins are well known in the art and include for example polyethylene, polycarbonate, polystyrene and like polymeric resinous materials.

[0035] The lid 40 component is shown in an isometric view in FIG. 5 and comprises a generally disc shaped closure member having an outer peripheral zone 54 and an inner or central zone 56. A skirt (or flange) 58 depends downwards from the outer peripheral zone 54 of the lid 40. It will be observed in FIG. 5 that the flange 58 depends downward from peripheral zone 54 of the lid member 40 to partially hide the underside of lid 40. The flange includes an inner surface which contains a means for sealingly engaging the lid with the open end of the cup. The side wall 42 of the cup 38 can also contain a fill level indicator 60 which identifies a maximum fill level for collecting a fluid specimen. The fill level indicator is positioned so that the fluid specimen will not exceed the capacity of the collection chamber 52 when the cup 38 is initially filled to the fill level indicator (i.e., before the lid is attached) and the lid 40 is attached to the cup 38. Positioned at the central zone 56 is an opening 62 to an elongated tubular receptacle 64, preferably offset towards the outer peripheral zone 52. The receptacle is formed by sidewalls 66 and lower wall 68, having an inner surface 70 and an outer surface 72, which are continuous with and part of the molded surface of the lid component 40. The receptacle 64 as defined by its sidewalls 66 and lower wall 68 projects inwardly into the chamber 52 of cup 38 and extends towards the bottom wall 46 of the cup 38, when lid 40 is attached to close the open end 44 of cup 38. The central portion of the lower wall 68 extends a further distance towards the bottom wall 46 of the cup 38 (when the lid 40 is attached to the cup 38). The central portion of the outer surface 72 of the lower wall 68 is preferably adjacent to the inner surface 48 of the closed end 46 of the cup 38 and offset from the central portion of the closed end 46, towards the sidewalls 42 of the cup 38. The outer surface 72 of the lower wall 68 has an opening 74 to a tubular cannula 76 located at the central portion of the lower wall 68.

[0036] The tubular cannula 76 is continuous with and part of the molded lower wall 68 of the receptacle 64. The cannula 76 has a first end defined by the opening 74 in the central portion of the lower wall 68 of the receptacle 64 and a second needle point 78 end which projects from the inner surface 70 of the lower wall 68 into the receptacle 64 in a position to pierce the stopper of an evacuated tube when the tube is received with its pierceable stopper end first into the receptacle. The cannula is in open communication between chamber 52 and an evacuated tube when the tube is inserted in the receptacle and the stopper is pierced. The needle point

78 end of the cannula 76 is recessed within the receptacle 64 at a depth from the opening 62 sufficient to prevent injury to a patient or attendant when handling the container, collecting a specimen, transporting the specimen or withdrawing a sample of the specimen. The needle point 78 of the cannula 76 is preferably recessed within the receptacle at a depth from the opening 62 below the fill level indicator 60 on the sidewall 42 of the cup 38, when the lid 40 is attached to close the open end 44 of cup 38.

[0037] A cannula pierceable self-sealing sleeve 80 is secured over the cannula 76, covering the second needle end 78 and preventing fluid communication between the chamber 52 and the receptacle 64. The sleeve 80 is pierceable to allow communication between the chamber 52 and the evacuated tube when the tube is inserted in the receptacle 64 (and the stopper is pierced) and self-sealing to prevent fluid communication between the chamber 52 and the receptacle 64 when the tube is retracted from the receptacle. The sleeve 80 is preferably a unitary device molded of any flexible, elastomeric material conventionally used for fabricating gas-proof closures. Representative of such materials are natural rubber (cis-1,4-polyisoprene, molecular weight 100,000 to 1,000,000), polyurethane elastomers, butyl rubber (copolymers of isobutylene and diolefins) and the like. Preferred elastomeric materials are those of low gas permeability such as butyl rubbers having a Shore A hardness of circa 35 to 80.

[0038] This structure is particularly advantageous in that it allows the operator to safely handle the container assembly 36 and to insert an evacuated tubular container into the receptacle 64 in the same manner previously described in reference to the previously described embodiment container 10. In this way, the operator can conveniently and safely withdraw biologically hazardous materials from chamber 52 into the inserted evacuated, tubular container. When a sufficient portion of biologically hazardous material has been withdrawn into the evacuated, tubular container from chamber 52, via cannula 76, the operator may remove the inserted tubular container from receptacle 64, interrupting communication of cannula 76 from the tubular container and preventing communication with the receptacle 64. Those skilled in the art will readily appreciate that the integral, unitary structure of the collection container 36 serves to protect the operator from an unnecessary exposure to potentially hazardous biological materials which may be contained within chamber 52.

[0039] Referring now to FIGS. 6-7, further details of the lid component 40 may be observed. FIG. 6 is a side elevation of lid 40 in cross section and FIG. 7 is a similar view with an air-evacuated tube inserted in the receptacle and forced over the needle point of the cannula. The inner surface 82 of flange 58 and the outer surface of the sidewalls 42 adjacent to the open end 44 of the cup 38 can include mating threads or other means for temporarily and sealingly attaching the lid 40 to the cup 38.

Other means for temporarily and sealingly attaching the lid 40 may include mating ridges or protrusions extending in an annular fashion to provide a snap-on attachable lid. Other means for temporarily and sealingly attaching the lid 40 to the cup 38 are also contemplated.

[0040] The elongated tubular receptacle 64 projects inwardly into the chamber 52 of cup 38 when lid 40 is placed on the open end 44 of the cup 38 and extends to a point so that the outer surface 72 of its lower wall 68 is adjacent to the inner surface 48 of the closed end 46 of the cup 38. The outer surface 72 of the lower wall 68 preferably extends to a distance of less than about 2 cm from the inner surface 48 of the closed end 46 of the cup 38 and, more preferably, less than about 1 cm from the inner surface 48 closed end 46 of the cup 38, when the lid 40 is sealed on the open end 44 of the cup 38.

[0041] The cannula 76 is continuous with an part of the molded lower wall 68 of the receptacle 64. Preferably, the lid 40 is molded from a polymeric resin as one continuous piece, including the receptacle 64 and the cannula 76. The needle point 78 of the cannula 76 is located within the receptacle 64 in a position to pierce the stopper 84 of an evacuated tube 86, when the tube is received with its stopper end first into the receptacle, and at a sufficient distance from the opening 62 of the receptacle 64 to prevent injury to an operator from an accidental needle stick during handling. The needle point 78 of the cannula 76 is recessed within the receptacle at a depth from the opening 62 substantially below the sealing flange 58 of the lid 40. This results in the needle point of the cannula 76 being located substantially below opening 62 of receptacle 64. Preferably, the needle point 78 is positioned so that the ratio of the distance between the opening 62 of the receptacle 64 and the needle point 78 to the distance between the needle point 78 and the inner surface 70 of the lower wall 68 of the receptacle 64 is at least about 3:1 and, more preferably, at least about 4:1. The needle point 78 preferably projects from the inner surface 70 of the lower wall 68 of the receptacle 64 to a minimum distance sufficient to reliably and repeatedly pierce the stopper 84 of an evacuated tube 86 and establish fluid communication between the chamber 52 of the cup 38 and the tube 86, when the tube is received with its stopper end first into the receptacle. The needle point 78 preferably projects from the outer or peripheral portion of the inner surface 70 of the lower wall 68 of the receptacle 64 to a distance of less than about 2.0 cm from the inner surface 70, more preferably, less than about 1.5 cm, and, most preferably, about 1.0 cm.

[0042] The cannula pierceable self-sealing sleeve 80 is secured over the cannula 76 and prevents fluid communication between the cannula 76 and the receptacle 64. The sleeve 80 is pierceable to allow communication between the cannula opening 74 and the evacuated tube 86, when the tube is inserted into the receptacle, stopper end first, and the stopper 84 is pierced by the

needle end 78 of the cannula 76. The sleeve 80 is made from a resilient flexible material which allows the sleeve 80 to be pierced and pushed down over the cannula 76 by the stopper 84 of the tube 86, as shown in FIG. 7, and allows the sleeve 80 to restore itself, to its original position when the tube is retracted and to reseal, preventing fluid communication between the cannula 76 and the receptacle 64, as shown in FIG. 6.

[0043] The container 10 or 36 according to the invention is intended to be used in the first instance by a patient, and then by a doctor, nurse or laboratory technician in the second instance for sampling of the collected specimen. The patient uses the container 10 or 36 by removing the entire cover assembly 12 or 40 and then providing the sample. The cover 12 or 40 is then reapplied by the patient, and the container 10 or 36 is given to the test person. That person inserts the evacuated specimen vial 22 or 86 into the receptacle 16 or 84 stopper end first until the needle point 30 or 78 pierces the pierceable stopper end. The vacuum of the vial 22 or 86 then causes a portion of the sample to be drawn up the cannula 24 or 76 into the vial 22 or 86. The vial 22 or 86 can then be withdrawn or retracted from the receptacle 16 or 64 and a second, third, etc. vial inserted and forced over the needle point 30 or 78 to withdraw additional portions of the sample. Once the final desired portion is withdrawn, the container 10 or 36 is then discarded or further handled as desired.

[0044] Those skilled in the art will appreciate the simple, unitary construction of the container 10 or 36 and the ease with and safety which it may be operated in association with air-evacuated, tubular containers of the type described in conjunction with the container embodiment 10 or 36. The protection that the containers 10 and 36 offer to the operator are evident. There are no loose parts in the container assembly which require separate manipulation for the transfer of contained materials and the container reseals itself upon withdrawing the evacuated sample tube.

Claims

1. A container assembly for collecting, transporting and dispensing a fluid specimen comprising:

a cup-shaped container having sidewalls joining a bottom wall and an opposed open end define a container interior for collecting said fluid specimen;

a lid attachable to said container to close said open end thereof, said lid having a central portion, a peripheral margin, a sealing flange at the periphery of the peripheral margin and a continuous, elongated receptacle having an opening located within the central portion for insertable receipt of an evacuated tube having a cannula pierceable stopper, said peripheral flange

extending from the peripheral margin towards the bottom wall of the container and making sealing engagement with the open end of the container when the lid is sealed on the container, said elongated receptacle including a lower wall extending from the central portion of the lid into the container interior and towards the bottom wall of the container when the lid is placed on the container;

a cannula supported by said lower wall of said receptacle with a first needle end positioned within the receptacle at a depth into said opening substantially below the sealing flange, in a position to pierce the stopper of an evacuated tube when said tube is received with its pierceable stopper end first into said receptacle, and a second needle end within the container interior so that communication between said container and said tube is established when said tube is inserted in the receptacle; and a self-sealing closure member preventing fluid communication between the container and the receptacle, said closure member allowing communication between the container and the tube when the tube is inserted in the receptacle and being self-sealing to prevent fluid communication between the container and the receptacle when the tube is retracted from the receptacle.

2. A container assembly of claim 1 wherein said elongated receptacle is generally cylindrical for accommodating said evacuated collection tubes.
3. A container assembly of claim 1, wherein said cannula is formed of a polymeric resin.
4. A container assembly of claim 3, wherein said plastic cannula is molded in place on the lower wall of said elongated receptacle.
5. A container assembly of claim 1, wherein said lid is screw attachable to said container.
6. A container assembly of claim 1, wherein said lid is snap-on attachable to said container.
7. A container assembly of claim 1, wherein the bottom wall of said container comprises an inner convex shaped surface and an outer concave shaped surface.
8. A container assembly of claim 7, wherein the opening of said elongated receptacle is offset from the center of the central portion of said lid, towards the peripheral margin of said lid, and the lower wall of said receptacle extends towards the bottom wall of the container at a location offset from the center of the said bottom wall, towards the sidewalls, when

the lid is placed on the container.

9. A container assembly of claim 8, wherein the second needle end of said cannula is flush with the lower wall of said elongated receptacle.
10. A container assembly of claim 1, wherein the lower wall of said elongated receptacle extends to a distance of less than 2 cm from the bottom wall of said container when the lid is placed on the container.
11. A container assembly of claim 10, wherein the lower wall of said elongated receptacle extends to a distance of less than 1 cm from the bottom wall of said container when the lid is placed on the container.
12. A container assembly of claim 1, wherein the first needle end is positioned at a location within the receptacle such that the ratio of the distance from the opening of said receptacle to said first needle end to the distance from the lower wall of said receptacle to said first needle end is at least about 3:1.
13. A container assembly of claim 12, wherein said ratio is at least about 4:1.
14. A container assembly of claim 1, wherein the first needle end is positioned at a location within the receptacle at a distance of less than about 2.0 cm from the lower wall of said receptacle.
15. A container assembly of claim 14, wherein the first needle end is positioned at a distance of less than about 1.5 cm from the lower wall of said receptacle.
16. A container assembly of claim 1, wherein said container is transparent.
17. A container assembly of claim 16, wherein said container further comprises a side wall having a fill level indicator which identifies the maximum fill level for collecting said fluid specimen.
18. A container assembly of claim 17, wherein said fill level indicator is located so that the fluid specimen will not exceed the capacity of said container when said container is initially filled to the fill level indicator and the lid is placed on the container.
19. A container assembly of claim 18, wherein said first needle end is positioned at a location within the receptacle at a depth from the opening substantially below said fill level indicator when the lid is placed on the container.
20. A container assembly of claim 1, wherein said self-sealing closure member comprises a cannula pierceable self-sealing sleeve covering the first

needle end of said cannula to prevent fluid communication between said container and said receptacle.

- 5 21. A container assembly of claim 20, wherein said sleeve is pierceable to allow communication between said container and an evacuated tube when the tube is inserted in the receptacle and is self-sealing to prevent fluid communication between said container and said receptacle when the tube is retracted from the receptacle.
- 10 22. A container assembly of claim 21, wherein said sleeve comprises a unitary device molded from a flexible, elastomeric material capable of resealing after being pierced by said cannula.
- 15 23. A container assembly for collecting, transporting and dispensing a fluid specimen comprising:
 - 20 a cup-shaped container having an open end defining a container interior for collecting said fluid specimen;
 - 25 a lid attachable to said container to close said open end thereof, said lid having a continuous, elongated receptacle having an opening located within the central portion for insertable receipt of an evacuated tube having a cannula pierceable stopper, said elongated receptacle including a lower wall adjacent the bottom wall when the lid is placed on the container;
 - 30 a cannula supported by said lower wall of said receptacle with a first needle end positioned within the receptacle at a depth into said opening substantially below said opening, in a position to pierce the stopper of an evacuated tube when said tube is received with its pierceable stopper end first into said receptacle, and a second needle end within the container interior so that communication between said container and said tube is established when said tube is inserted in the receptacle; and
 - 35 a self-sealing closure member preventing fluid communication between the container and the receptacle, said closure member allowing communication between the container and the tube when the tube is inserted in the receptacle and being self-sealing to prevent fluid communication between the container and the receptacle when the tube is retracted from the receptacle.
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 - 45
 - 50
 - 55

FIG. 1

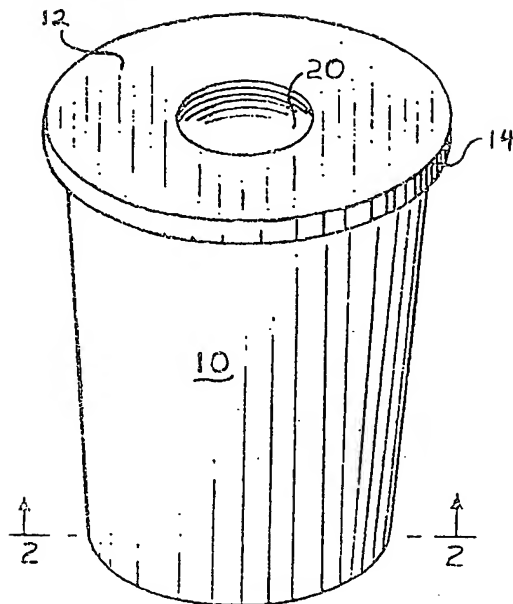


FIG. 2

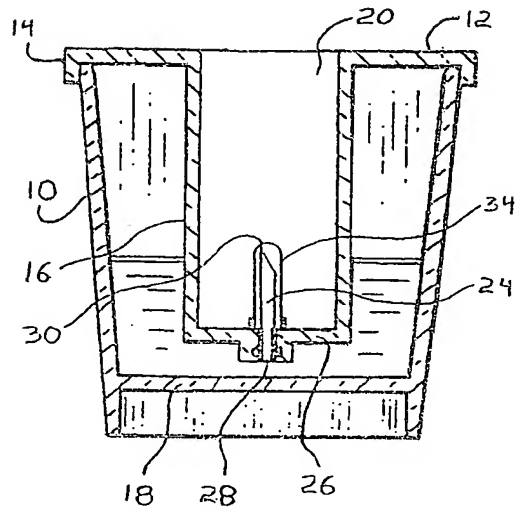


FIG. 3

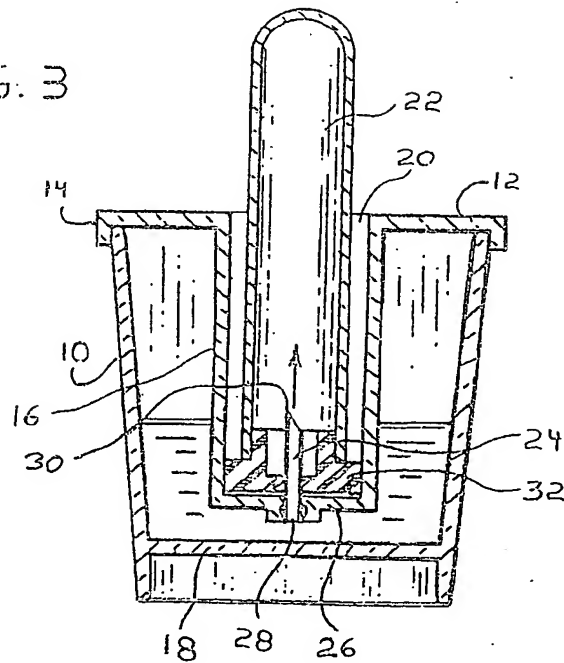


FIG. 4

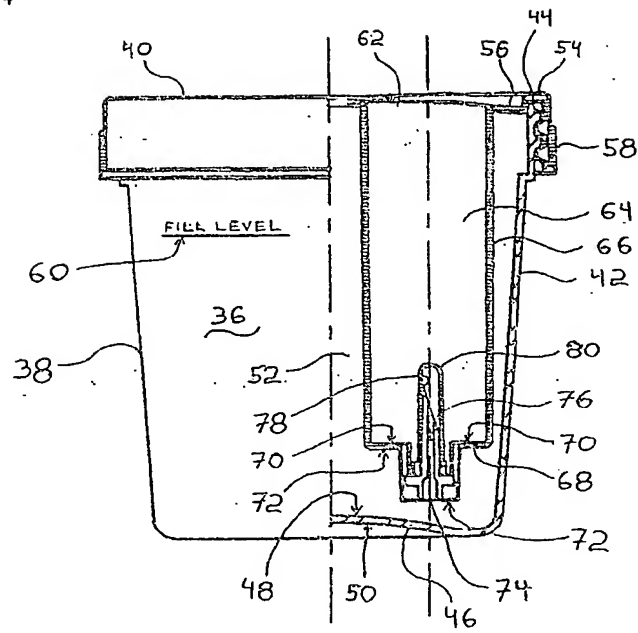


FIG. 5

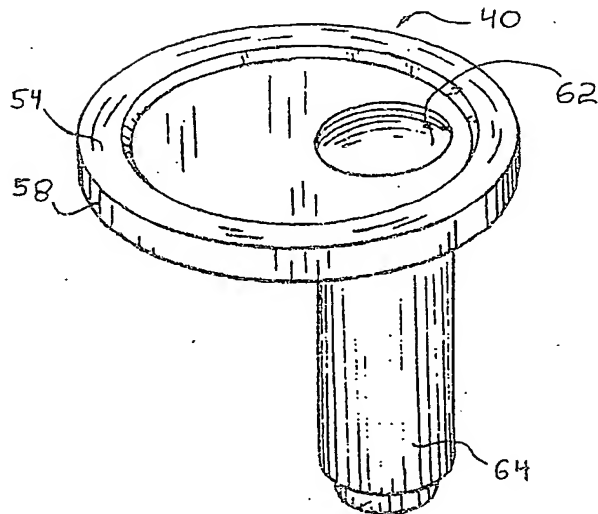


FIG. 6

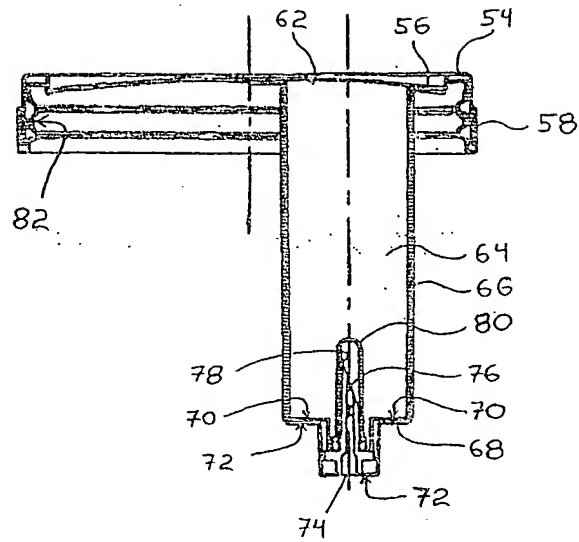
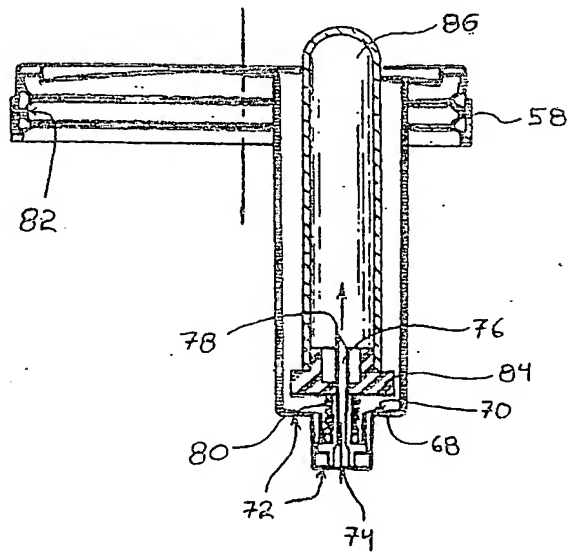


FIG. 7





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 02 07 8750

DOCUMENTS CONSIDERED TO BE RELEVANT					
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)		
Y	GB 2 060 583 A (BECTON-DICKINSON CO) 7 May 1981 (1981-05-07) * the whole document *	1-3,9-23	A61B10/00		
Y	US 4 116 066 A (MEHL JACK J ET AL) 26 September 1978 (1978-09-26) * the whole document *	1-3,9-23			
A	US 6 235 010 B1 (GOLABEK JR ROBERT S ET AL) 22 May 2001 (2001-05-22) * abstract; figures 1,9 *	1-6,23			
A	US 4 559 649 A (BURNETT PATRICIA A) 24 December 1985 (1985-12-24) * abstract; figure 3 *	1,7,23			
A	EP 0 787 987 A (MINA LTD) 6 August 1997 (1997-08-06) * abstract; figure 1 *	1,8,23			
A	US 4 934 547 A (GOLIAS TIPTON A ET AL) 19 June 1990 (1990-06-19) * abstract; figure 1 *	1,23	<table border="1"> <thead> <tr> <th>TECHNICAL FIELDS SEARCHED (Int.Cl.7)</th> </tr> </thead> <tbody> <tr> <td>A61B B01L</td> </tr> </tbody> </table>	TECHNICAL FIELDS SEARCHED (Int.Cl.7)	A61B B01L
TECHNICAL FIELDS SEARCHED (Int.Cl.7)					
A61B B01L					
The present search report has been drawn up for all claims					
Place of search BERLIN		Date of completion of the search 4 December 2002	Examiner Hansen, S		
<table border="0"> <tr> <td> CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document </td> <td> T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document </td> </tr> </table>				CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document	T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document
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EPO FORM 1503 03.02 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 02 07 8750

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

04-12-2002

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 2060583	A	07-05-1981	US 4300404 A	17-11-1981
			AU 537285 B2	14-06-1984
			AU 6173980 A	19-03-1981
			BR 8005728 A	17-03-1981
			DE 3029631 A1	12-03-1981
			ES 8203772 A1	16-07-1982
			FR 2465219 A1	20-03-1981
			JP 1480055 C	10-02-1989
			JP 56064639 A	01-06-1981
			JP 63026867 B	31-05-1988
			MX 150953 A	24-08-1984
			NZ 194679 A	12-04-1983
			SE 443125 B	17-02-1986
			SE 8006285 A	11-03-1981
US 4116066	A	26-09-1978	NONE	
US 6235010	B1	22-05-2001	NONE	
US 4559649	A	24-12-1985	NONE	
EP 0787987	A	06-08-1997	US 5429803 A	04-07-1995
			EP 0787987 A2	06-08-1997
			AT 159588 T	15-11-1997
			AU 645689 B2	20-01-1994
			AU 1781492 A	17-11-1992
			CA 2085741 A1	19-10-1992
			DE 69222826 D1	27-11-1997
			DE 69222826 T2	19-02-1998
			EP 0535212 A1	07-04-1993
			JP 3244504 B2	07-01-2002
			JP 6501101 T	27-01-1994
			WO 9218844 A1	29-10-1992
			US 5471994 A	05-12-1995
			US 6210909 B1	03-04-2001
US 4934547	A	19-06-1990	US 5849505 A	15-12-1998
			US 6106483 A	22-08-2000
			US 5301685 A	12-04-1994
			US 4736859 A	12-04-1988
			AU 602378 B2	11-10-1990
			AU 8312887 A	11-08-1988
			CA 1301709 A1	26-05-1992
			EP 0279126 A2	24-08-1988
			US 4799597 A	24-01-1989

EPO FORM P469

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82